II. 510(k) Summary

NOV 1 4 2000

[As described in CFR 807.92]

Submitted by: Welch Allyn Inc.
95 Old Shoals Road
Arden, NC 28704

Contact Person: Joseph D. Buchanan
Senior Quality Assurance Engineer

Date Prepared: 14 August 2000

Proprietary Name: Welch Allyn Spot Check Device

Common Name: Vital Signs Measurement Device

Classification Name: Class II 870.1130 Noninvasive Blood Pressure System

Predicate Device: Welch Allyn Vital Signs Monitor
Welch Allyn, Inc.
510(k) Document Control Number *K951193*

Description of the Device:

The Welch Allyn Spot Check Device is not a monitor, but a one time vital signs measurement device. This product will not have continuous monitoring capability with timed cycle intervals, memory, or any various programmable alarm features. The device is intended to provide the physician, physician's assistant, or nurse, facing high patient traffic or multiple tasks, a cost effective method to determine a one-time vital signs reading on the spot. The base unit will have non-invasive blood pressure (BP) measurement. Options will also be offered such as SureTemp® thermometry, Nellcor® pulse oximetry (SpO_2), mounting bracket, and rolling stand. The device may be interfaced with an external printer via an infrared port.

The Welch Allyn Spot Check Device is designed to non-invasively measure systolic and diastolic blood pressure, pulse rate, temperature and oxygen saturation (SpO2) for adult and pediatric patients. The Welch Allyn Spot Check Device also calculates Mean Arterial Pressure (MAP). All blood pressure, pulse, temperature and SpO2 values are displayed on a large, easy-to-read LCD display, and may be printed via an external thermal printer, as desired. The rechargeable battery and wide variety of

mounting accessories make the Welch Allyn Spot Check Device convenient for many locations.

The Welch Allyn Spot Check Device is intended for use in a wide variety of health care settings. This includes hospital departments, alternate care settings, such as physician offices, freestanding ambulatory care and surgery centers, health clinics and nursing homes. ***The Welch Allyn Spot Check Device is not intended for the monitoring of patients.*** The Welch Allyn Spot Check Device is not intended for use in environments which are not supervised by a health care practitioner.

Indications/Contraindications For Use of the Device:

The Welch Allyn Spot Check Device Check Device is intended for measurement of blood pressure, pulse rate, temperature and oxygen saturation (SpO_2) of adult and pediatric patients. The device is not designed, sold or intended for use except as indicated.

The Welch Allyn Spot Check Device is not designed for use with neonates. To ensure pediatric blood pressure accuracy and safety, note that the Welch Allyn small cuff (5200-03) and the small One Piece Cuff (5200-13) are the smallest cuffs approved for use with young children and infants. The circumference of the child's arm must fit within the range markings on the cuff.

The Welch Allyn Spot Check Device should not be used on patients who are linked to heart/lung machines.

The Welch Allyn Spot Check Device is not designed for use of axillary temperature option above three years of age in children.

The Welch Allyn Spot Check Device is not intended to monitor patients vital signs.

The Welch Allyn Spot Check Device is not defibrillator proof.

Technological Characteristics:

The Welch Allyn Spot Check Device Check Vital Signs Device utilizes the same BP Algorithm, the same temperature technology and algorithm, and the same pulse oximetry OEM as the Welch Allyn Vital Signs Monitor. The following table summarizes the similarities between the Welch Allyn Spot Check Device and the Welch Allyn Vital Signs Monitor.

Table 1

Specifications & Technological Comparison Between the Welch Allyn Spot Check Device and the Welch Allyn Vital Signs Monitor.

	Welch Allyn Spot Check Device	**Welch Allyn Vital Signs Monitor.**
Blood Pressure		
BP Determination Method	Oscillometric	Oscillometric
Auto Zero	Yes	Yes
Initial Cuff Inflation	160 (Default). Operator may change this default. Options are 120, 140, 160, 180, 200, 240 and 280.	160 (Default). Operator may change this default. Options are 120, 140, 160, 180, 200, 240 and 280.
Measurement Range		
Systolic	60-250 mmHg	60-250 mmHg
Diastolic	30-160 mmHg	30-160 mmHg
Heart Rate	40-200 bpm	40-200 bpm
Measurement Accuracy		
Cuff Pressure	+/- 3 mmHg	+/- 3 mmHg
Blood Pressure	AAMI SP10-1992	AAMI SP10-1992
Heart Rate	+/- 5% (BP Determination) +/- 3% (SpO2 Determination)	+/- 5% (BP Determination) +/- 3% (SpO2 Determination)
BP Time Intervals (Min.)	NA	Manual, Stat, 1, 3, 4, 5, 10, 15, 30, 45, 60, 90 min.
Measurement time (sec.)	20-45 typical, 165 max.	20-45 typical, 165 max.
Mean Arterial Pressure	Calculated	Calculated
Nellcor® OEM SpO2		
SpO2 Measurement	Yes	Yes
OEM Model Used	MP205	MP205
Measurement Range		
SpO2	40-100%	40-100%
Heart Rate	25-245 bpm	40-200 bpm
Measurement Accuracy		
SpO2	70-100% +/- 3% <70% unspecified	70-100% +/- 3% <70% unspecified
Heart Rate	+/- 3 bpm	+/- 3 bpm
Alarm Adjustable Ranges		
SpO2 Low	NA	70-100%
SureTemp® OEM Temperature		
Temperature	Yes	Yes
Measurement Range	86F (30C) to 109.4F (43.0C)	84F (28.9C) to 108F (42.2C)
Measurement Accuracy	per ASTM E1112-86 (1991)	per ASTM E1112-86 (1991)
Temperature Determination	Normal Mode: 4 sec (Oral), 10 sec (Axillary), 15 sec (Rectal) Monitor Mode: 3 minutes	Normal Mode: 4 sec (Oral), 10 sec (Axillary), 15 sec (Rectal) Monitor Mode: 3 minutes
Overall System		

Patient Population	Pediatric/Adult	Pediatric/Adult
Data Communications	IR Capable Communication	RS232 Communications
Display Type	Custom LCD	7 Segment LED PCB
Low Battery Indicators	Symbol on LCD begins to flash when low battery voltage is detected	LED illuminates when low battery voltage is detected.
Number of readings stored in memory	No readings are stored	Last 99 readings are stored
Battery Charge Time	90% Capacity in 12 hours. Unit will operate and charge the battery simultaneously	90% Capacity in 12 hours. Unit will operate and charge the battery simultaneously
Battery Life	150 typical readings	200 typical readings
Warranty	Two Years	Two Years
Height	9.70 inches (24.64 cm)	6.5 inches (16.5 cm)
Length	5.72 inches (14.53 cm)	8.6 inches (21.8 cm)
Depth	4.73 inches (12.01 cm)	5.0 inches (12.7 cm)
Weight	4.25 lbs	6 lbs
Operating Temperature	10 to 40 C (except temperature which is 16 to 40 C)	10 to 40 C (except temperature which is 16 to 40 C)
Humidity Range	15 to 90% RH non-condensing	15 to 90% RH non-condensing
Altitude Range	-170m (557 ft) to +4877 (16,000 ft)	-170m (557 ft) to +4877 (16,000 ft)
Storage Temperature	-20 to 50 C	-20 to 50 C
Battery	Lead Acid, with external recharge capability	Lead Acid, with external recharge capability

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 14 2000

Joseph D. Buchanan
Senior Quality Engineer
Welch Allyn, Inc.
95 Old Shoals Road
Arden, NC 28704-9739

Re: K002530
Trade Name: Welch Allyn Spot Check Device
Regulatory Class: II (two)
Product Code: 74 DXN
Dated: August 14, 2000
Received: August 16, 2000

Dear Mr. Buchanan:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the ~~device~~ is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act

for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

VII. Indications for Use Statement

510(k) Number: ~~Unknown~~ K002530

Device Name: Welch Allyn Spot Check Device

Indications for use: The Spot Check Device is intended for measurement of blood pressure, pulse rate, temperature and oxygen saturation (SpO_2) of adult and pediatric patients. The device is not designed, sold or intended for use except as indicated.
The Welch Allyn Spot Check Device is not designed for use with neonates. To ensure pediatric blood pressure accuracy and safety, note that the Welch Allyn small cuff (5200-03) and the small One Piece cuff (5200-13) are the smallest cuffs approved for use with young children and infants. The circumference of the child's arm must fit within the range markings on the cuff.
The Welch Allyn Spot Check Device should not be used on patients who are linked to heart/lung machines.
The Welch Allyn Spot Check Device is not designed for use of axillary temperature option above three years of age in children.
The Welch Allyn Spot Check Device is not intended to monitor patients vital signs.
The Welch Allyn Spot Check Device is not defibrillator proof.

(Please Do Not Write Below This Line - Continue On Another Page If Needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K002530

Prescription Use_____ Or Over-The-Counter Use_____

(Per 21 CFR 801.109)